As explained below, this Amendment After Final should be entered because remaining claims 60, 61, 63-68, 70-72, 74-79, 113, and 114 are allowable. Even if the Examiner continues to believe one or more of the rejections of those claims are still applicable, Applicants submit that the Examiner should indicate that he will grant entry of the present Amendment After Final upon the filing of a Notice of Appeal, because the proposed claim cancellation reduces the issues for appeal.

The proposed cancellation of claims 62, 69, 73, 80-90, 92-101, 103-112, and 115-159 should obviate all of the claim rejections under 35 U.S.C. §§ 102(b) and (e) and 103, except the Section 102(b) rejections based on U.S. Patent No. 4,840,615 to Hancock et al. ("Hancock") and U.S. Patent No. 4,857,053 to Dalton, and the Section 103(a) rejection based on U.S. Patent No. 4,000,740 to Mittleman in view of U.S. Patent No. 5,718,682 to Tucker. As explained below, those claim rejections should be withdrawn because the sole remaining independent claims 60 and 70 are allowable over those references.

Section 102 rejection based on Hancock

Applicants submit that independent claims 60 and 70 are patentably distinguishable over Hancock. For example, this reference lacks any disclosure or suggestion of an access port device including, among other elements, a septum between upper and lower body parts, "wherein an outer surface of the septum forms a portion of an exterior surface of the device," as recited in claims 60 and 70.

Hancock discloses a self-sealing injection reservoir adapted to be implanted. In the Office Action, the Examiner has apparently alleged that a sealing plate 28 shown in

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Figs. 2-5 of Hancock corresponds to the septum recited in claims 60 and 70. The Examiner has cited Hancock at col. 5, lines 16-20 for the asserted disclosure of a "septum outer surface [that] is exposed exteriorly." Contrary to the Examiner's assertion, however, that cited portion of Hancock merely mentions that the sealing plate 28 shown in Figs. 2-5 is preferably made from biocompatible silicone rubber, but that "it does not need to be biocompatible unless it is exposed for contact with living tissue (not shown)." Hancock does not include any explicit disclosure or other suggestion of any part of the plate 28 forming a portion of an exterior surface, and Hancock even acknowledges that its contact with living tissue is "not shown." Furthermore, it is not clear how the arrangement discussed at col. 5, lines 16-20 would be configured because the drawings of Hancock show an outer layer 26 completely covering the sealing plate 28 so that no part of the sealing plate 28 contacts living tissue or defines an exterior surface.

Applicants submit that Hancock's mere mention of the possibility of the plate 28 being exposed to contact living tissue does not provide inherent disclosure of the plate 28 having an outer surface forming a portion of an exterior surface of Hancock's injection reservoir. In other words, contrary to the Examiner's assessment at page 5 of the Office Action, merely because Hancock discloses that the sealing plate 28 could be exposed to living tissue does not therefore require the sealing plate 28 to form an exterior surface. There could be numerous arrangements that might expose Hancock's plate 28 to contact living tissue without plate 28 necessarily having an outer surface forming an exterior surface portion of the injection reservoir. For example, the exposure to tissue contact that is mentioned in Hancock might possibly refer to an arrangement in

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which the sealing plate 28 is completely covered by the outer layer 26, as shown in Figs. 2-5, but is formed of biocompatible material so that if a flap or some other structural passage forms in the outer layer 26 during use, movement of such a flap would temporarily place biocompatible material of the plate 28 in contact with living tissue. Accordingly, Hancock at col. 5, lines 16-20 does not disclose, either explicitly or inherently, "an outer surface of the septum [that] forms a portion of an exterior surface of the device," as recited in claims 60 and 70.

Section 102 rejection based on Dalton

Dalton also lacks disclosure or suggestion of an access port device including, among other elements, a septum between upper and lower body parts, "wherein an outer surface of the septum forms a portion of an exterior surface of the device," as recited in claims 60 and 70.

Dalton discloses a drug delivery port including a matrix septum material. Though not clear in the Office Action, the Examiner appears to be alleging that web 30 of Dalton corresponds to the recited upper body part, and that Dalton's elastomeric layer 25 corresponds to the recited septum. In the paragraph bridging pages 5 and 6 of the Office Action, the Examiner has asserted that Dalton discloses an "embodiment without the [outer] covering [66], [where] the septum's outer surface forms an exterior surface (col. 5, line 66 - col. 6, line 48)." Contrary to the Examiner's assertion, each drug delivery port embodiment disclosed in Dalton has either an outer layer coating 66 (col. 6, lines 28-29, and Figs. 4-6), an outer potting layer (col. 6, lines 64-66, and col. 7, lines 16-17), or an outer elastomer layer (col. 7, lines 28-32) completely covering the

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elastomeric layer 25 so that the elastomeric layer does not define an exterior surface of the drug delivery port. The portion of Dalton cited by the Examiner (col. 5, line 66 - col. 6, line 48) does not disclose the mysterious "embodiment without the outer covering" that the Examiner relies on as the basis for his claim rejection. Accordingly, claims 60 and 70 are patentably distinguishable from Dalton.

Section 103 rejection based on Mittleman in view of Tucker

Claim 60 recites an access port device to be implanted in a patient's body wherein upper and lower body parts are formed of "implantable, biocompatible material."

Mittleman discloses an injection site 10 having a main body portion 12, first and second inlets 14, 16, and a diaphragm 26. As discussed in the Background of the Invention section of Mittleman, the injection site disclosed in that reference is a device commonly used in a hospital setting when it is desired to combine a medicament with a parental fluid (e.g., I.V. fluid) being fed to a patient intravenously. Col. 1, lines 7-11. Such devices are always positioned along tubing placed between the parental fluid source and the delivery device (e.g., needle) inserted in the patient without ever being implanted in the patient. Accordingly, there is no disclosure or suggestion of "implantable, biocompatible material."

The Examiner asserts, at page 4 of the Office Action, that it would be obvious to modify Mittleman with titanium material disclosed in Tucker "to provide a device compatible with bioactive fluids." This reasoning is clearly based on hindsight gleaned from the present application. As mentioned above, the injection site of Mittleman would

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not be implanted within the body of a patient and, as such, there would be no plausible reason why one of ordinary skill in the art would look to Tucker for any asserted teaching of implantable, biocompatible material. Tucker provides no teaching or suggestion to modify the material of a non-implanted, parental injection site such as that taught by Mittleman. Moreover, one of ordinary skill in the art would not chose titanium to form the injection site of Mittleman because such a material is rather expensive and difficult to form into a given shape, especially compared to many suitable plastic materials that would readily accommodate "bioactive fluids." Therefore, there is no motivation to combine the references as proposed by the Examiner.

Conclusions

For at least the reasons set forth above, Applicants respectfully request that the Examiner enter this Amendment, reconsider the application, and issue a Notice of Allowability in a timely manner.

The Office Action contains numerous assertions relating to the claims and the related art. Applicants decline to automatically subscribe to any assertion in the Office Action, regardless of whether any such assertion is discussed above.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: June 17, 2003

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